

SUMMARY OF CLAIMS

Claims 1-19 and 39-57 are withdrawn. Claims 27, 37, 62, and 72 are currently amended. Claims 20-38 and 58-72 are pending. Reconsideration is respectfully requested in light of the following remarks.

REMARKS

I. Claim Objection

The Examiner has objected to claims 27 and 62 as encompassing non-elected species. Applicant have amended claims 27 and 62 to remove non-elected species from the claims. Withdrawal of the objection is respectfully requested.

II. Claim Rejections – 35 U.S.C. §112

The Examiner has rejected claims 20-38 and 58-72 under 35 U.S.C. §112, first paragraph, because according to the Examiner “the specification, while being enabling for dermal color alteration treatment by laser therapy in conjunction with administration of macrophage colony stimulating factor (MCSF, a cytokine), does not reasonably provide enablement for a method for altering coloration by administering an effective amount of a cytokine or a tumor necrosis factor e.g. TNF-alpha in the absence of laser therapy.” Office Action, p.2

According to MEPE 2164.01, “[t]he standard for determining whether the specification meets the enablement requirement . . . is whether that disclosure . . . contained sufficient information regarding the subject matter of the claims as to enable one skilled in the pertinent art to make and use the claimed invention.” Moreover, “[t]he specification need not disclose what is well known to those skilled in the art and preferably omits that which is well known to those skilled and already available to the public.” *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed Cir. 1991)

Applicant respectfully traverses the above rejection because the burden in presenting a *prima facie* case of non-enablement has not been met. It is well established that compliance with the enablement requirement does not turn on whether an example is disclosed. In fact, “[t]he specification need not contain an example if the invention is otherwise disclosed in such manner that

one skilled in the art will be able to practice it without undue experimentation.” *In re Borkowski* 422 F2d 904, 908, 164 USPQ 642, 645 (CCPA 1970). In the present case, the specification clearly points out how the cytokine or tumor necrosis factors alter coloration of a dermal region. See Figure 1 and paragraphs 0027-0035.

Furthermore, there is no reason stated by the Examiner to support the assertion that the “unpredictability in factors involved in pigmentation and proliferation of melanocytes” would hence require undue experimentation for a person of skill in the art to be able to use the invention. The disclosure contains sufficient content for a person of skill in the art, e.g. a dermatological medical doctor, to use the invention without undue experimentation, including use of the claimed substances and use of color alteration therapies such as laser therapy.

Based on the foregoing, as a *prima facie* case of a non-enablement rejection under 35 U.S.C. §112, first paragraph has not been made, and Applicant respectfully requests withdrawal of the rejection.

The Examiner has also rejected claims 20-38 and 58-72 under 35 U.S.C. §112, first paragraph, for lack of written description.

Applicants respectfully traverse the above rejection as the Examiner has failed to satisfy the burden required to show lack of written description. According to MPEP 2163 “[a] description as filed is **presumed** to be adequate, unless or until sufficient evidence to the contrary has been presented by the examiner to rebut the presumption.” Moreover, “[a]n objective standard for determining compliance with the written description requirement is, does the description clearly allow **persons of ordinary skill in the art** to recognize that he or she invented what is claimed.” See MPEP 2163.02. In order to satisfy the written description requirement, “each claim limitation must be expressly, implicitly or inherently supported in the originally filed disclosure.” See MPEP 2163 II(3)(ii)(b).

Applicant respectfully traverses the above rejection, as the Examiner has failed to rebut the presumption that “a person skilled in the art at the time the application was filed would not have recognized that the inventor was in possession of the invention.” In particular, the description of cytokines and tumor necrosis factors in Applicant’s disclosure does provide a precise definition that a person of skill in the art would recognize and understand, e.g. a chemical name. There is no

ambiguity about the identity of a substance referred to as “a cytokine [which] is selected from the group consisting of interleukins, lymphokines, tumor necrosis factors, interferons, chemokines, and growth factors.” Specification, Paragraph 0028. The above are well recognized and well defined **names or nomenclature** for cytokines known by a person of skill in the art. Cytokines are further described in paragraphs 0028-0034 of the specification and in Figure 1.

Based on the foregoing, Applicant respectfully requests withdrawal of the above rejection under 35 U.S.C. §112, first paragraph.

III. Claim Rejections – 35 U.S.C. § 103

The Examiner has rejected claims 20-21, 26-37, 58-58, and 61-72 under 35 U.S.C. 103(a) as being unpatentable over Cohen, *et al.* (Medical Hypotheses 45: 83-85, 1994) (“Cohen”) in view of Jimenez-Cervantes, *et al.* (J.Cell Sci. 114:2335-2344, 2001) (“Jimenez-Cervantes”) and Solis, *et al* (Dermatol. Surg. 28:83-87, 2002) (“Solis”).

Applicant respectfully traverses the above rejection as the Examiner has failed to establish a *prima facie* case of obviousness. As stated in the MPEP 2143, to establish a *prima facie* case of obviousness, the prior art references must teach or suggest all of the claimed limitations.

As currently pending, independent claim 20 covers a “method for altering coloration of a dermal region comprising **administering an effective amount of a tumor necrosis factor**” and independent claim 58 covers “a method for altering coloration of a dermal region comprising **administering an effective amount of a cytokine excluding a macrophage colony-stimulating factor.**” None of the references cited by the examiner disclose the steps of “administration of an effective amount of a tumor necrosis factor” or “administering an effective amount of a cytokine excluding a macrophage colony-stimulating factor.” Rather, Cohen discloses the use of macrophage colony-stimulating factor as an adjuvant after tattoo removal using laser therapy. Cohen, page 83, paragraph 3 - page 84, paragraph 1. Applicant specifically does not use macrophage colony-stimulating factor. Jimenez-Cervantes discloses the use of hydrogen peroxide to inhibit tyrosine hydroxylase activity of mouse and human melanoma cells. Jimenez-Cervantes, page 2343, paragraph 3, lines 1-2. Solis teaches the use of topical imiquimod to alter coloration of a dermal region. Solis, page 85, paragraph 1, lines 6-9.

As the above three references fail to teach, either independently or in combination, all of the claimed limitations of the pending claims, Applicant respectfully requests withdrawal of the above rejection under 35 U.S.C. §103.

The Examiner has rejected claims 20-25, 58-60 under 35 U.S. C. §103(a) as being unpatentable over Cohen and Jimenez-Cervantes in view of Beade et al. (Am. J. Clin. Dermatol. 2(1): 21-25, 2001) ("Beade").

Applicant respectfully traverses the above rejection as the Examiner has failed to establish a *prima facie* case of obviousness. As stated above, independent claim 20 covers a "method for altering coloration of a dermal region comprising ***administering an effective amount of a tumor necrosis factor***" and independent claim 58 covers "a method for altering coloration of a dermal region comprising ***administering an effective amount of a cytokine excluding a macrophage colony-stimulating factor***." None of the above references (Cohen, Jimenez-Cervantes, and Beade) disclose the step of "administration of an effective amount of a tumor necrosis factor" or administering an effective amount of a cytokine excluding a macrophage colony-stimulating factor." For example, Beade teaches that tattoos can be removed using lasers. Beade, page 22, paragraph 7-paragraph 8. A discussion of Cohen and Jimenez-Cervantes is above.

As the above three references fail to teach, either independently or in combination, all of the claimed limitations of the pending claims, Applicant respectfully requests withdrawal of the above rejection under 35 U.S.C. §103.

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CONCLUSION

In light of the remarks set forth above, Applicant believes that he is entitled to a letters patent. Applicant respectfully solicits the Examiner to expedite the prosecution of this patent application to issuance. Should the Examiner have any question, the Examiner is encouraged to telephone the undersigned.

The Commissioner is authorized to charge any underpayment or credit any overpayment to Deposit account No. 23-2415 (Attorney Docket No. 30864-701.201) for any matter in connection with this response, including any fee for extension of time, which may be required.

Respectfully submitted,

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By: _____



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